Multicenter Blinded RCT To Determine Safety And Effectiveness Of Venous PTA For Multiple Sclerosis

The BRAVE DREAMS Trial Design And Progress: Will It Settle The Controversy

There is huge variability in the prevalence of CCSVI in MS, across studies. For this reason the link between MS and CCSVI and the associated treatment with venous PTA have been a subject of controversy and debate.

Despite this, there are a number of observational studies reporting possible advantages by treating CCSVI in MS with balloon angioplasty.

The available evidence is scarce and NICE encouraged research on PTA for CCSVI in MS, in the form of robust controlled clinical trials.

The Department of Public Health, Emilia Romagna Region (Italy) decided to fund a randomized multicenter clinical trial in 2012.

THE BRAVE DREAMS TRIAL (Brain Venous Drainage Exploited Against MS)

Trial registration: Clinicaltrials.gov NCT01371760

- Multicenter
- Randomized
- Double blinded
- Sham controlled
- Randomization 2:1
- Intention to treat analysis
- Funding Department of Public Health, Emilia Romagna Region (Italy)

CCSVI treatment: does it work and why?

Fixing the jugular flow reduces ventricle volume and improves brain perfusion

NICE

NORMAL CLEARANCE TIME < 2SEC
THE BRAVE DREAMS TRIAL
Centers and Organizations

- Each center under the responsibility of a neurologist
- Interventionalist/vascular surgeon possibly in a different Hospital. Arm assignment was electronically available only the day of the treatment.
- Two assessors of the functional primary outcome. The same assessed QoL questionnaires for secondary endpoints.
- MR acquisition same protocol at 1.5 T and centralized lecture

THE BRAVE DREAMS TRIAL
Inclusion criteria

- Age 18-65 years-MS diagnosis,
- CCSVI screened with ECD
- Patients under care for at least 2 years at the enrolling centre
- Relapsing remitting and secondary progressive
- Expanded Disability Status Scale (EDSS) 2 - 5.5
- Disease duration ≤15 years

Exclusion criteria

- Previous venous angioplasty, therapy with Fingolimod, Cladribine or Laquinimod within 3 months prior to enrolment treatment

TWO PRIMARY END-POINTS

New T1 Gad+ MRI lesion
New/enlarged T2 lesions

SECONDARY END-POINTS

Fatigue
Impact of bladder incontinence
Anxiety and depression

THE BRAVE DREAMS TRIAL

Eligibility
- Clinical assessment
- ECD assessment
- Functional test
- MRI

Time

Randomization to procedure-sham 2:1
- Functional test
- Neurological assessments
- QoL

Bottom line ECD assessment mandatory for inclusion into the trial

THE BRAVE DREAMS TRIAL

199 patients assessed for eligibility
69 ineligible
69 randomized to intervention
130 enrolled
130 completed protocol
93 assigned to Percutaneous Transluminal venous Angioplasty (PTA)
44 assigned to venography without balloon angioplasty (Sham)

125 compliant protocol
• Brave DREAMS trial is a randomized double blinded sham controlled trial to assess safety and effectiveness of venous PTA for MS treatment
• The effect of treatment on neurological function is for the first time objectively measured
• MRI outcomes are the traditional parameters evaluated in clinical practice as well as in trial on drugs
• Evaluation also of QoL endpoints
• Brave DREAMS will provide novel information on the effects of the intervention